

Department of Veterans Affairs

§ 16.123

from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

(Approved by the Office of Management and Budget under Control Number 0990-0260.)

[56 FR 28012, 28021, June 18, 1991, as amended at 70 FR 36328, June 23, 2005]

§ 16.118 Applications and proposals lacking definite plans for involvement of human subjects.

Certain types of applications for grants, cooperative agreements, or contracts are submitted to departments or agencies with the knowledge that subjects may be involved within the period of support, but definite plans would not normally be set forth in the application or proposal. These include activities such as institutional type grants when selection of specific projects is the institution's responsibility; research training grants in which the activities involving subjects remain to be selected; and projects in which human subjects' involvement will depend upon completion of instruments, prior animal studies, or purification of compounds. These applications need not be reviewed by an IRB before an award may be made. However, except for research exempted or waived under § 16.101 (b) or (i), no human subjects may be involved in any project supported by these awards until the project has been reviewed and approved by the IRB, as provided in this policy, and certification submitted, by the institution, to the department or agency.

§ 16.119 Research undertaken without the intention of involving human subjects.

In the event research is undertaken without the intention of involving human subjects, but it is later proposed to involve human subjects in the

research, the research shall first be reviewed and approved by an IRB, as provided in this policy, a certification submitted, by the institution, to the department or agency, and final approval given to the proposed change by the department or agency.

§ 16.120 Evaluation and disposition of applications and proposals for research to be conducted or supported by a Federal Department or Agency.

(a) The department or agency head will evaluate all applications and proposals involving human subjects submitted to the department or agency through such officers and employees of the department or agency and such experts and consultants as the department or agency head determines to be appropriate. This evaluation will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the research to the subjects and others, and the importance of the knowledge gained or to be gained.

(b) On the basis of this evaluation, the department or agency head may approve or disapprove the application or proposal, or enter into negotiations to develop an approvable one.

§ 16.121 [Reserved]

§ 16.122 Use of Federal funds.

Federal funds administered by a department or agency may not be expended for research involving human subjects unless the requirements of this policy have been satisfied.

§ 16.123 Early termination of research support: Evaluation of applications and proposals.

(a) The department or agency head may require that department or agency support for any project be terminated or suspended in the manner prescribed in applicable program requirements, when the department or agency head finds an institution has materially failed to comply with the terms of this policy.

(b) In making decisions about supporting or approving applications or proposals covered by this policy the department or agency head may take into account, in addition to all other

§ 16.124

eligibility requirements and program criteria, factors such as whether the applicant has been subject to a termination or suspension under paragraph (a) of this section and whether the applicant or the person or persons who would direct or has have directed the scientific and technical aspects of an activity has have, in the judgment of the department or agency head, materially failed to discharge responsibility for the protection of the rights and welfare of human subjects (whether or not the research was subject to federal regulation).

§ 16.124 Conditions.

With respect to any research project or any class of research projects the department or agency head may impose additional conditions prior to or at the time of approval when in the judgment of the department or agency head additional conditions are necessary for the protection of human subjects.

PART 17—MEDICAL

DEFINITIONS AND ACTIVE DUTY

Sec.

- 17.30 Definitions.
- 17.31 Duty periods defined.

PROTECTION OF PATIENT RIGHTS

- 17.32 Informed consent and advance health care planning.
- 17.33 Patients' rights.

TENTATIVE ELIGIBILITY DETERMINATIONS

- 17.34 Tentative eligibility determinations.

HOSPITAL OR NURSING HOME CARE AND MEDICAL SERVICES IN FOREIGN COUNTRIES

- 17.35 Hospital care and medical services in foreign countries.

ENROLLMENT PROVISIONS AND MEDICAL BENEFITS PACKAGE

- 17.36 Enrollment—provision of hospital and outpatient care to veterans.
- 17.37 Enrollment not required—provision of hospital and outpatient care to veterans.
- 17.38 Medical benefits package.
- 17.39 Certain Filipino veterans.
- 17.40 Additional services for indigents.

EXAMINATIONS AND OBSERVATION AND EXAMINATION

- 17.41 Persons eligible for hospital observation and physical examination.
- 17.42 Examinations on an outpatient basis.

38 CFR Ch. I (7–1–06 Edition)

HOSPITAL, DOMICILIARY AND NURSING HOME CARE

- 17.43 Persons entitled to hospital or domiciliary care.
- 17.44 Hospital care for certain retirees with chronic disability (Executive Orders 10122, 10400 and 11733).
- 17.45 Hospital care for research purposes.
- 17.46 Eligibility for hospital, domiciliary or nursing home care of persons discharged or released from active military, naval, or air service.
- 17.47 Considerations applicable in determining eligibility for hospital, nursing home or domiciliary care.
- 17.48 Compensated Work Therapy/Transitional Residences program.
- 17.49 Priorities for outpatient medical services and inpatient hospital care.

USE OF DEPARTMENT OF DEFENSE, PUBLIC HEALTH SERVICE OR OTHER FEDERAL HOSPITALS

- 17.50 Use of Department of Defense, Public Health Service or other Federal hospitals with beds allocated to the Department of Veterans Affairs.
- 17.51 Emergency use of Department of Defense, Public Health Service or other Federal hospitals.

USE OF PUBLIC OR PRIVATE HOSPITALS

- 17.52 Hospital care and medical services in non-VA facilities.
- 17.53 Limitations on use of public or private hospitals.
- 17.54 Necessity for prior authorization.
- 17.55 Payment for authorized public or private hospital care.
- 17.56 Payment for non-VA physician and other health care professional services.

USE OF COMMUNITY NURSING HOME CARE FACILITIES

- 17.57 Use of community nursing homes.
- 17.60 Extensions of community nursing home care beyond six months.

COMMUNITY RESIDENTIAL CARE

- 17.61 Eligibility.
- 17.62 Definitions.
- 17.63 Approval of community residential care facilities.
- 17.64 Exceptions to standards in community residential care facilities.
- 17.65 Duration of approval.
- 17.66 Notice of noncompliance with VA standards.
- 17.67 Request for a hearing.
- 17.68 Notice and conduct of hearing.
- 17.69 Waiver of opportunity for hearing.
- 17.70 Written decision following a hearing.
- 17.71 Revocation of VA approval.
- 17.72 Availability of information.